UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOHN SEALOCK, on behalf of himself, individually, and on behalf of all others similarly-situated, **Plaintiff,** **-against-** **COVANCE, INC.,** **Defendant.**	**Case No.: 17-cv-5857 (JMF)**

DEFENDANT COVANCE, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO STRIKE THE CLASS ALLEGATIONS IN PLAINTIFF'S AMENDED COMPLAINT

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Defendant Covance, Inc., by and through their attorneys, Kelley Drye & Warren LLP, respectfully submits this memorandum of law in support of its Motion to strike the class allegations in Plaintiff's Amended Complaint pursuant to Federal Rule of Civil Procedure 12(f).

PRELIMINARY STATEMENT

Covance, Inc. ("Covance") is a global contract research organization that provides critical clinical services to pharmaceutical and biotechnology companies to manage and execute drug trials. To do so, Covance is charged with ensuring drug trials are executed accurately and safely. Quality control protocols of these drug trials are executed, implemented, and managed by Covance's Clinical Research Associates ("CRA"). CRAs are the direct and most essential link between the clinical sites, where drug trials are administered, and Covance's pharmaceutical clients. Drug trials require extreme caution, as accuracy of data and execution of research protocols, have a direct effect on both drug development (and ultimately public health) and drug trial patient safety. CRAs ensures quality control where integrity and judgment are of the utmost importance.

This case is brought by one CRA who claims that he and all other CRAs do not perform professional and quality control functions and thus are misclassified under federal and state wage-and-hour laws. The Amended Complaint in this matter, however, pleads no plausible class for a category of employees that are patently exempt from overtime laws. Plaintiff, instead, has crafted the scope of the proposed class and pled allegations in a manner that effectuates a fishing expedition for individual claims. Indeed, the proposed class definition is facially defective as "fail-safe" because it requires individual litigation of individual claims as a predicate for class membership.

CRAs are responsible for quality control. Their work environments are deliberately flexible to manage the unique circumstances of each drug trial. Plaintiff does not plead any

supporting facts or substantive allegations from which to plausibly infer that his own alleged personal circumstances are applicable to others. Plaintiff's failure is not surprising as no class-wide policy exists that would make Plaintiff's factual allegations similar to other putative class members. As such, Plaintiff's class and collective allegations should be stricken from the Amended Complaint.

"Fail-safe" Class Actions Are Impermissible

The proposed class definition includes any employee who "did not receive . . . legally-required overtime wage[s]" and were not provided with "accurate" wage statements and notices under New York Labor Law. By definition, only those that suffered overtime violations are members of the class. Those excluded would, in turn, be excluded from impacting threshold issues such as commonality, typicality, and predominance. Courts have repeatedly struck down the use of such class descriptions because it side-steps the Rule 23 prerequisites of maintaining a class or collective action and inherently forces individualized litigation.

A Modified Class Definition Would Include a Substantial Number of Employees who Suffered No Injuries and Inevitably Require Litigation of Individualized Claims

Nor will modifying the proposed class definitions to remove the terms "legally required" and "accurate" fix the remaining defects in the Amended Complaint.

First and foremost, Plaintiff's alleged work duties establish that he and others suffered no injury whatsoever. Plaintiff was not misclassified – he is the critical intermediary between patient testing and drug development. Indeed, the duties he describes make him administratively exempt under the Fair Labor Standards Act and New York Labor Law. His independent judgment is crucial to **ensure quality control** of drug trials – that can only be accomplished by "monitoring" clinical sites. As evidenced by the declarations submitted with this Motion, Plaintiff is not alone; the job duties of a CRA exempt them from overtime.

Secondly, Plaintiff pleads a work environment that is highly individualized and, therefore, cannot serve as a basis for class treatment. Specifically, Plaintiff alleges that due to a fixed daily schedule without breaks, he worked a nominal number of overtime hours. Plaintiff does not allege any policy or practice by Covance that infers other employees would be subject to the same schedule restrictions. Plaintiff's schedule was entirely self-imposed. More importantly, Plaintiff worked from home performing duties that inherently permit flexible work schedules. The express nature of his job makes any uniform work environment or schedule inflexibility unfeasible. Absent a specific and identifiable policy, it is implausible that all other potential class members worked a schedule the same as Plaintiff without breaks in the comfort of their own home.

Covance's supporting declarations confirm that each CRA's work schedule, including daily hours, is individualized, self-created and not the product of any common policy or practice by Covance. Covance CRAs manage clinical trials for many drugs for many different pharmaceutical companies at different clinical sites with a wide number of trial patients. Each drug trial has their own specific protocols set by Covance's pharmaceutical client with different scheduling needs. Thus, flexible and individualized scheduling is mandated and the norm for CRAs due to the nature of the job and facilitated by their remote work environment.

Potential Disclosure of Sensitive Drug Trial Information Tips the Scale Against Permitting Class Discovery

Class discovery would be inappropriate here where: (1) the nature of Plaintiff's work and that of the putative class members would invariably require scrutiny into highly sensitive pharmaceutical testing data; and (2) Plaintiff fails to demonstrate a minimal factual basis for class treatment. Drug trials involve highly confidential information related to drug development, public health, and private patient medical information. Even with a protective order, the risk of disclosure is disproportional to the speculative nature of Plaintiff's class claims. In these circumstances,

Plaintiff has an affirmative obligation to demonstrate some minimal basis to justify a potential class. Class discovery without an adequate basis for class treatment would result in a fishing expedition placing an excessive burden on Covance and this Court to prevent needless risk of disclosure.

STATEMENT OF FACTS

A. COVANCE'S CLINICAL RESEARCH ASSOCIATES

Covance is a life sciences research company that contracts with pharmaceutical companies to assist them in the development of drugs and medical devices. (Bertolo Decl. ¶ 4). To perform this important work, Covance employs CRAs to oversee and monitor the administration of clinical trials. (Knight Decl. ¶ 3). Although CRAs do not actually conduct the trials, they are responsible for administering nearly every aspect of the clinical trial to ensure clinical trial data is accurate and that the clinical trial is safe for study participants. (Dudimah Decl. ¶ 4).

i. The Individualized Nature of a Clinical Trial

CRAs are assigned to one or two clinical trials at any given time. (Rudofsky Decl. ¶ 7). Each clinical trial is guided by a unique protocol which explains how the trial is to be conducted. (Id. ¶ 10). The protocol sets forth the objectives of the trial, the methods by which the trial is designed to operate, the procedures that must be followed in order to safeguard the health of participants, and sets forth certain metrics to assess the effectiveness of the clinical trial. (Id.). CRAs are responsible for interpreting the protocols to ensure that the clinical trial conforms to the requirements of the protocol. (Bertolo Decl. ¶ 10).

ii. CRAs Varying Job Duties and Responsibilities

CRAs have general oversight and front-line quality control responsibility over the clinical trial sites to which they are assigned. (Knight Decl. ¶ 3); (Bertolo Decl. ¶ 4); (Dudimah Decl. ¶ 4). Before a clinical trial begins, CRAs are responsible for conducting a pre-trial qualification visit

to the offices of physicians who are scheduled to participate in the trial. (Dudimah Decl. ¶ 10). During the pre-trial qualification visit, a CRA evaluates whether a physician is qualified to conduct the trial and, based on the evaluation, the CRA issues a recommendation to the clinical trial sponsor. (Id. ¶ 11). In making their recommendation, CRAs use their discretion to assess factors beyond the written criteria that would call into question a physician's qualifications for the trial, such as whether the site's staff seems too busy or whether there are enough staff members to adequately conduct the trial. (Knight Decl. ¶ 7); (Dudimah Decl. ¶ 11); (Rudofsky Decl. ¶ 11); (Austin Decl. ¶ 8). A CRA's recommendation as to whether a physician qualifies to conduct a clinical trial is usually adopted by the clinical trial sponsor. (Dudimah Decl. ¶ 11).

Subsequent to the pre-trial qualification visit, CRAs conduct a site initiation visit to train qualified physicians and their staff regarding the proper procedures required in the clinical trial. (Rudofsky Decl. ¶ 12); (Austin Decl. ¶ 10). A CRA is responsible for conducting this training and answering any questions that a physician or staff may have regarding the clinical trial, including the proper interpretation of the clinical trial's protocol. (Bertolo Decl. ¶ 11). CRAs use their judgment to identify any ambiguities in a protocol or variances that have an impact on the quality and integrity of the research pool. (Id. ¶ 10); (Austin Decl. ¶ 10). Where a CRA cannot reconcile an ambiguity on his or her own, the CRA is encouraged to raise unresolved issues with the CRA's clinical team leader. (Rudofsky Decl. ¶ 5).

During the clinical trial, CRAs are responsible for performing regular site visits to ensure that the trial is being conducted consistent with a CRA's proper guidance, and that the trial is free from errors that could taint or discredit the trial's results. (Dudimah Decl. ¶ 14); (Knight Decl. ¶ 11); (Bertolo Decl. ¶ 12); (Austin Decl. ¶ 12). In so doing, CRAs use their experience and judgment to identify potential problems in the clinical trial data based upon the information

provided by the site. (Dudimah Decl. ¶¶ 9, 15); (Knight Decl. ¶¶ 11, 12, 14); (Bertolo Decl. ¶¶ 14); (Rudofsky Decl. ¶¶ 13-14); (Austin Decl. ¶ 13). For example, CRAs are responsible for monitoring the clinical trial data and requesting further clarification from the clinical trial site if a CRA believes that there has either been an error in entry or recording of data or if the data reveals a potential issue with patient safety. (Rudofsky Decl. ¶ 13); (Hillock Decl. ¶ 8); (Austin Decl. ¶¶ 13, 15).

After every site visit, CRAs prepare a written report of their observations. (Dudimah Decl. ¶ 17); (Knight Decl. ¶ 16); (Bertolo Decl. ¶ 14); (Rudofsky Decl. ¶ 15); (Lee Decl. ¶ 9); (Austin Decl. ¶ 16). Although these reports require CRAs to identify specific information regarding the clinical trial site, CRAs also use these reports to notify the clinical trial sponsor of any other issues that the CRA believes is relevant or pertinent to the study. (Id.).

iii. Covance Has No Policy Governing CRA Work Schedules

There is no predictability when it comes to a CRAs work schedule because of the nature of a clinical trial. (Dudimah Decl. ¶¶ 18-20); (Knight Decl. ¶¶ 18-21); (Bertolo Decl. ¶¶ 17-20); (Rudofsky Decl. ¶¶ 16-17); (Lee Decl. ¶¶ 11-13); (Hillock Decl. ¶¶ 9-10); (Austin Decl. ¶ 7). Each clinical trial has a protocol that identifies how often a CRA must visit each clinical trial site. (Dudimah Decl. ¶ 18); (Knight Decl. ¶ 9); (Rudofsky Decl. ¶ 16); (Lee Decl. ¶ 9); (Hillock Decl. ¶ 9). The frequency with which a CRA has to visit a clinical trial site varies depending upon whether the particular protocol has a fixed visiting schedule or whether the protocol provides for visits based upon the amount of data collected. (Dudimah Decl. ¶ 18). The amount of time a CRA is on site for any one visit will vary from visit-to-visit, site-to-site, and trial-to-trial. (Bertolo Decl. ¶¶ 13, 18); (Knight Decl. ¶ 9); (Rudofsky Decl. ¶ 16). Therefore, depending upon the clinical trial, the schedule of a CRA is never the same, day-to-day. (Rudofsky Decl. ¶ 16); (Lee Decl. ¶ 12). Nor is the schedule of one CRA the same as any other. (Bertolo Decl. ¶¶ 17-21).

Due to the nature of a CRAs monitoring responsibilities, Covance has no policy or practice concerning a CRA's work schedule. (Id. ¶ 19); (Austin Decl. ¶ 17). CRAs have no set schedule and their individual schedules change significantly from day-to-day based on the needs of the specific clinical trial. (Rudofsky Decl. ¶ 16); (Knight Decl. ¶ 20). As long as CRAs visit the clinical trial sites as necessary and are able to obtain the information required to advance the trial consistent with the trial's protocol, CRAs can arrange their schedules to be as convenient for them as possible. (Knight Decl. ¶ 20); (Bertolo Decl. ¶ 19).

For this reason, Covance has no company-wide policy or practice requiring CRAs to work a certain number of hours per week. (Dudimah Decl. ¶ 21); (Knight Decl. ¶ 20). It is a CRA's responsibility to plan visits to clinical trial sites by contacting the clinical trial site directly. (Rudofsky Decl. ¶ 16); (Lee Decl. ¶ 11). Covance managers do not set CRA clinical trial site visit schedules or CRA schedules in general. (Dudimah Decl. ¶ 22); (Bertolo Decl. ¶ 21); (Austin Decl. ¶ 17). In fact, CRAs generally have no day-to-day contact with their supervisors. (Hillock Decl. ¶ 11); (Bertolo Decl. ¶ 21). Most CRAs communicate with their supervisors once every other week, and Covance has no policy or uniform practice concerning how and when a CRA communicates with his or her supervisor. (Knight Decl. ¶ 22); (Rudofsky Decl ¶ 17); (Austin Decl. ¶ 17).

Along with setting their own schedules, CRAs have the absolute freedom to take meal breaks or any other type of breaks whenever they choose. (Dudimah Decl. ¶ 21); (Knight Decl. ¶ 21); (Bertolo Decl. ¶ 20); (Rudofsky Decl. ¶¶ 16-17); (Lee Decl. ¶ 14); (Hillock Decl. ¶ 10); (Austin Decl. ¶ 17). Their supervisors have no role in setting any break schedules as doing so would be nearly impossible given the varying schedule and travel responsibilities of CRAs. (Id.).

B. PLAINTIFF'S AMENDED COMPLAINT

On September 6, 2017, Plaintiff filed his Amended Complaint alleging four types of claims: (i) failure to pay overtime under the Fair Labor Standards Act ("FLSA"); (ii) failure to pay overtime under the New York Labor Law ("NYLL"); (iii) failure to provide wage statements under NYLL § 195(3); and (iv) failure to provide a wage notice at hire pursuant to NYLL § 195(1). See Am. Compl. ¶¶ 40-62. Plaintiff seeks to bring his claims on behalf of himself, individually, and on behalf of all other similarly-situated persons as a collective action pursuant to § 216(b) of the FLSA and as a class action pursuant to Federal Rule of Civil Procedure ("FRCP") 23. See id. ¶¶ 5-6.

As to Plaintiff's class action claim pursuant to FRCP 23, Plaintiff defines the class as follows:

> Current and former clinical research associates, or those working in a similar role, who during the applicable NYLL limitations period, performed any work for Defendant in New York, and who: (1) did not receive compensation at the legally-required overtime wage rate of pay for each hour worked per week over forty; and/or (2) were not provided with accurate wage statements on each payday pursuant to NYLL § 195(3); and/or (3) were not provided with an accurate wage notice at the time of hire pursuant to NYLL § 195(1).

Id. ¶ 18.

Plaintiff's allegations arise from his former employment as a CRA with Covance from July 28, 2016, to May 17, 2017. Id. During such time, Plaintiff alleges that his job responsibilities consisted of many of the tasks described above, including monitoring clinical trial sites, closing out sites at the end of clinical drug trials, and completing other tasks such as maintaining study files. Id. ¶ 29. Plaintiff alleges that he completed a substantial amount of his duties from his residence in the Bronx, New York. Id. ¶ 28.

Regarding Plaintiff's alleged hours worked per week, Plaintiff alleges that he worked between forty-two and one-half and forty-five hours per week. Id. ¶ 30. Plaintiff calculates his alleged worktime by claiming that Covance required that he "start[] his workday at **approximately** 9:00 a.m. and end[] between **approximately** 5:30 p.m. and 6:00 p.m., while **rarely** providing him with an uninterrupted break during each workday." Id. (emphasis added). He provides no allegations connecting his circumstances to others except for a general and conclusory statement that Covance "treated" others "in the same manner." Id. ¶ 37. Plaintiff additionally alleges that he failed to receive "accurate" wage notices at the time of hire, and on each occasion Covance paid Plaintiff, presumably based on his classification as an exempt employee. Id. ¶ 53-62.

ARGUMENT

Under Rule 12(f) of the Federal Rules of Civil Procedure, the Court may strike from a pleading any "insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed R. Civ. Proc. 12(f). Rule 23(c)(1) directs district courts to determine "at an early practicable time" whether the proposed class satisfies the requirements for class certification. Fed. R. Civ. Proc. 23(c)(1); Davito v. Amtrust Bank, 743 F. Supp. 2d 114 (E.D.N.Y. 2010) (granting motion to strike class allegations).

Under Rules 23 and 12(f), "this Court has authority to strike class allegations prior to discovery if the complaint demonstrates that a class action cannot be maintained. See, e.g., Davito, 743 F. Supp. 2d at 115–16; Rahman v. Smith & Wollensky Rest. Grp., Inc., 2008 WL 161230, at *3 (S.D.N.Y. Jan. 16, 2008). A defendant can successfully move to strike class allegations by demonstrating "from the face of the [c]omplaint that it would be impossible to certify the alleged class regardless of the facts [the] [p]laintiffs may be able to obtain during discovery." Hidalgo v. Johnson & Johnson Consumer Co., 148 F. Supp. 3d 285 (S.D.N.Y. 2015) (quoting Mayfield v. Asta Funding, 95 F. Supp. 3d 685, 696 (S.D.N.Y. 2015)).

Here, striking Plaintiff's class definition is proper because Plaintiff pleads a fail-safe class on the face of his Amended Complaint. Further, an amendment to the pleadings would be futile because the alleged class members largely consist of exempt individuals or involve highly individualized claims such as Plaintiff's. Along with the fact that a class action cannot be maintained in this matter, permitting any discovery is not warranted given the highly sensitive nature of clinical trials, including patient health information.

I. PLAINTIFF'S FAIL-SAFE CLASS CANNOT BE CERTIFIED AND CANNOT BE FIXED BY MODIFICATION

A. Plaintiff's Class Definition is a Facially Defective "Fail-Safe" Class.

Plaintiff proposes a class of CRAs who: (a) did not receive "legally-required overtime" compensation; and (b) were not provided with "accurate" wage statements and notices pursuant to the NYLL. Plaintiff's proposed class can only include people who suffered violations of law. Thus, it is an impermissible fail-safe class.

Courts have routinely concluded that when class membership depends on a determination of a question of liability, the proposed class is "fail-safe" and cannot be certified. See Mazzei v. Money Store, 288 F.R.D. 45, 55 (S.D.N.Y. 2012); Spread Enterprises, Inc. v. First Data Merch. Servs. Corp., 298 F.R.D. 54, 69 (E.D.N.Y. 2014); see also Messner v. Northshore Univ. Healthsystem, 669 F.3d 802, 825 (7th Cir. 2012); Randleman v. Fid. Nat. Title Ins. Co., 646 F.3d 347, 352 (6th Cir. 2011); Kamar v. Radio Shack Corp., 375 Fed. App'x 734, 736 (9th Cir. 2010). Such a class "is unfair to defendants, it prevents an adverse judgment being entered against plaintiffs, and it is unmanageable because the members of the class could only be known after a determination of liability." Hicks v. T.L. Cannon Corp., 35 F. Supp. 3d 329, 356–57 (W.D.N.Y. 2014).

Here, membership in Plaintiff's proposed class is wholly dependent on whether a putative plaintiff received "legally required" overtime pay or legally "accurate" wage notices and statements. In effect, CRAs would be excluded from the class if they performed administratively exempt duties, did not work overtime hours, and received proper wage notices and statements. Determining whether or not each CRA qualified for overtime, and whether or not, as a result, each CRA received accurate wage statements, would have to be made on an individualized basis – without regard to typicality, commonality, predominance, or numerosity as a class. Even if these inquiries could be made on a class wide basis, the result risks the conclusion that only a handful of potential CRAs are class members. Such a conclusion defeats numerosity. Class certification should be denied on this ground alone.

B. Plaintiff's Class Definition Cannot Be Modified.

Merely removing the phrases "legally required" or "accurate" will not bring a class within the scope of Rule 23. Plaintiff's work conditions, namely his schedule, is individualized in nature and could not be the basis of a common reason for class-wide liability. As pled, with or without the benefit of Covance's supporting affidavits, it is implausible that a class could be formed: (a) without the inclusion of a substantial number of exempt individuals who have no injury at all; and (b) without the need for individualized claims that differ substantially from Plaintiff's allegations.

C. A Modified Class Will Inevitably Include a Substantial Number of Exempt Employees.

If a class is "defined so broadly that it includes a great number of members who for some reason could not have been harmed by the defendant's allegedly unlawful conduct, the class is defined too broadly to permit certification." Messner, 669 F.3d at 824. The Second Circuit has explained that while a defendant may bear the burden of an exemption in an individual overtime/misclassification case, the Court shall give equal weight to affirmative defenses when

considering the viability of a class action. See Myers v. Hertz Corp., 624 F.3d 537, 550-51 (2d Cir. 2010) (affirming denial of class certification because "general and largely inconclusive" testimony of similar responsibilities between putative class members require "individual factual analysis" would be insufficient to common theory of liability).

The administrative exemption under the NYLL applies to work by an individual:

> (a) whose primary duty consists of the performance of office or nonmanual field work directly related to management policies or general operations of such individual's employer;
>
> (b) who customarily and regularly exercises discretion and independent judgment;
>
> (c) who regularly and directly assists an employer, or an employee employed in a bona fide executive or administrative capacity (e.g., employment as an administrative assistant); or who performs, under only general supervision, work along specialized or technical lines requiring special training, experience or knowledge; and
>
> (d) who is paid [a certain minimal salary].

12 N.Y.C.R.R. § 142-2.14(c)(4)(ii).

Here, Plaintiff states that his "main duties consisted of monitoring clinical sites" during pharmaceutical drug trials and "clos[ing] out clinical sites" at the end of the trial. See Am. Compl. ¶ 29. As the self-described monitor, he is the front-line for drug trial quality control on behalf of Covance and its pharmaceutical clients. While clinics performed the actual pharmaceutical testing and patient facing affairs, he managed all the administrative and operational functions of the clinical trial such as monitoring the status of: "recruitment (of study patients), study supplies, medical data entry, and updated study and regulatory documents." See id. As such, the proposed class is presumptively exempt based upon Plaintiff's own description of his job duties.

Further, the supporting declarations of the CRAs confirm the same applicability of the administrative exemption to a CRA's work. In more specific terms, CRAs perform the following tasks:

- Identify protocol deviations and document deviations pursuant to protocols and good clinical practice. (Rudofsky Decl. ¶ 14); (Dudimah Decl. ¶¶ 14-15); (Knight Decl. ¶ 14).
- Train investigators and their staff on the interpretation of protocols and act as the first line of contact for clinical trial sites when any issues or questions arise. (Austin Decl. ¶ 10); (Bertolo Decl. ¶ 11); (Rudofsky Decl. ¶ 12).
- Evaluate whether proposed physicians qualify to conduct clinical trials and issue reports with recommendations. (Knight Decl. ¶ 7); (Dudimah Dec.¶ 10); (Austin Decl. ¶¶ 8-9).
- Review patient data to identify any inaccurate data or questionable trends that could impact patient safety. (Bertolo Decl. ¶ 12); (Knight Decl. ¶¶ 11, 14).

All of the above duties further confirm that CRAs will be administratively exempt. See Zannikos v. Oil Inspections (USA.), Inc., 605 F. App'x 349 (5th Cir. 2015) (holding that "marine superintendents" whose primary duty "included observing oil transfers to verify that performance was accurate, legal, and safe" performed office or non-manual work and qualified for the administrative exemption). Thus, a modified class will unavoidably be composed of a substantial number of exempt CRAs rendering class treatment inappropriate.

D. A Modified Class will Inevitably be Highly Individualized.

The sparseness of the Amended Complaint, brought by a single plaintiff, does not demonstrate any plausible set of commonly litigated facts. Instead, Plaintiff's own alleged work

conditions and duties clearly show that typicality, commonality and predominance are implausible because other putative class members would have to have had: (a) worked fixed and continuous hours in a day; and (b) denied themselves rest breaks in the comfort of their own homes. Indeed, and by his own admission, Plaintiff remotely managed clinical facilities undergoing pharmaceutical drug trial testing and had no duties that mandated a fixed schedule; his schedule was a product of his own creation. The declarations submitted herein confirm that he and others worked flexible schedules (while taking breaks as freely, and for as long as their own discretion allowed) and exercised independent discretion in the management and execution of the protocols. (Knight Decl. ¶¶ 12, 14, 20); (Rudofsky Decl. ¶ 16); (Dudimah Decl. ¶ 21).

This Court has held that class treatment would be inappropriate when policies that affect how overtime hours may be required or accumulated would vary so greatly as to require individualized determinations. See Ruiz v. Citibank, N.A., 93 F. Supp. 3d 279, 295 (S.D.N.Y. 2015) (denying class certification because the plaintiffs failed to demonstrate that appropriate policies have reliably translated themselves into inappropriate managerial behavior across the width and breadth of the class). Here, class treatment would be inappropriate because each CRA's work schedule was truly individualized due to variances caused by personal preferences and the protocols of each clinical trial to which each CRA is assigned. (Dudimah Decl. ¶ 18); (Knight Decl. ¶ 9); (Rudofsky Decl. ¶ 16); (Lee Decl. ¶ 9); (Hillock Decl. ¶ 9). More importantly, Plaintiff cannot identify a single unifying policy or practice that would plausibly suggest a class-wide reason for overtime hours. See Ruiz, 93 F. Supp. 3d at 295 (denying class certification on the ground that although some employees performed "off the clock" work, the cause of the overtime and minimum wage violations were due to unique situations to each potential class member and not on a company wide basis).

Similarly, wide variation in CRA schedules would be the direct result of the specific demands of each drug protocol and the manner in which each CRA sets his or her own schedule, pursuant to the goals of the protocol. Covance manages clinical trials for many drugs for many different pharmaceutical companies at different clinical sites with a wide number of trial patients. Each drug trial has its own protocols set by Covance's pharmaceutical clients, each with different scheduling needs. For example, each protocol may determine how often a CRA must physically visit each clinical trial site. (Lee Decl. ¶ 11). Some protocols may have a fixed visiting schedule. (Dudimah Decl. ¶ 18). Others require visits based upon the amount of data collected. (Id.). CRAs generally have no day-to-day contact with their supervisors. (Id.); (Knight Decl. ¶ 18). Flexible scheduling is essential, as CRAs are typically assigned to one or two drug trials. (Austin Decl. ¶ 6); (Rudofsky Decl. ¶ 7). As such, CRAs will set their own schedules without the input of Covance's management, so long as they execute their duties in accordance with the protocols. (Rudofsky Decl. ¶¶ 16-17) (Austin Decl. ¶ 17).

The Amended Complaint is devoid of any allegations that substantively or sufficiently connect his personal circumstances to other CRAs. See Diaz v. Electronics Boutique of Am., Inc., 2005 WL 2654270 (W.D.N.Y. Jan. 7, 2005) (holding that specific allegations do not rescue a putative class representative's claims from being "insufficiently specific beyond [his] own [respective] circumstances"). He baldly concludes that other CRAs were subject to similar treatment. Plaintiff, also, does not identify a policy or practice through which one could infer Covance, on a company wide basis, required a fixed schedule or a certain number of hours per week. Plaintiff pleads a work environment that demonstrates inherent flexibility in how he determines his own schedule. It is implausible that, based on the remote work environment and the nature of Plaintiff's duties, other CRAs would schedule their work in a similar fashion.

(Rudofsky Decl. ¶¶ 7, 16-17); (Bertolo ¶¶ 17-19); (Hillock Decl. ¶ 6). Irrespective of whether other CRAs exist that worked over-time hours, the reasons and causes of such hours would be the result of highly differing work environments, performance goals, and policies of direct supervisors. See Ruiz, 93 F. Supp. 3d 279, 295 (finding typicality, commonality and predominance is not met because any uncompensated overtime hours are likely caused by individual circumstances of personal bankers and the practices of their respective and different branch locations).

With or without Covance's supporting declarations, it is clear that Plaintiff's work hours (and lack of breaks) is a product of his own making and not a universal or common policy amongst CRAs. (Bertolo Decl. ¶¶ 17-20); (Rudofsky Decl. ¶ 16). Covance does recognize that such declarations (coupled with his own pleadings) does not eliminate Plaintiff's opportunity to litigate his own personal claims. His circumstances, nevertheless, demonstrate that he is the exception. Thus, class treatment would be inappropriate. See Diaz, 2005 WL 2654270, at *7 (holding that a class is inappropriate if the putative class representative's circumstances are unique to other putative class members).

As such, reformation of Plaintiff's class definition is not possible.

II. DISCOVERY INTO PLAINTIFF'S ALLEGATIONS IS INAPPROPRIATE

Plaintiff's deliberate attempt to pursue a "fail-safe" class, coupled with the implausibility of class-wide treatment, demonstrates a lack of intent to litigate a class action in a proper manner. Any potential class discovery would only be formulated in a "fail-safe" manner in the unfounded hopes of back-dooring into a class, or worse, searching for and soliciting additional individual claims. Class discovery would inevitably require individualized inquiries into protocols for every putative class member because no unifying policy or practice exists. These protocols (and the work product produced by putative class members) contain highly sensitive drug trial details for

various clients and products, as well as personal and private health data for drug trial participants. (Hillock Decl. ¶ 7); (Lee Decl. ¶ 8).

This Court has held that class discovery is inappropriate (and shall be denied) when "discovery demands impacted on privacy concerns" and the "class action representations in the complaint are speculation." In Wills v. Amerada Hess Corp. 1999 WL 500142, *1 (S.D.N.Y. July 15, 1999), a plaintiff, as personal representative of the estate of an individual who allegedly died of cancer resulting from hazardous exposure during employment, alleged that at least 25 other employees were injured in similar circumstances. The plaintiff filed a motion to compel discovery and for sanctions, in order to compel discovery related to each and every vessel the plaintiff worked, as well as the work and medical records for all employees who worked alongside the plaintiff. Judge Patterson denied plaintiff's motion for discovery because the plaintiff could not identify one specific class member that suffered the same injury, and therefore, found that plaintiff had no actual basis to pursue a class action. In short, this Court concluded that the plaintiff was "engaged in a fishing expedition for potential plaintiffs." Id.; see also Rosell v. Wells Fargo Bank, 2013 WL 4079178, at *1 (N.D. Cal Aug. 1, 2013) (holding that: (1) plaintiff failed to adequately allege facts sufficiently plausible to suggest a Rule 23 Class; and (2) that it would be inappropriate "to do some discovery to see . . . the shape of the class allegations").

Here, the Amended Complaint evokes the same issues related to privacy, sensitive information, and lack of a basis for class treatment from the onset. Each protocol, which is specific to each individual clinical trial, dictates the frequency with which CRAs must make onsite visits, and identifies the duties and performance requirements of each putative class member. (Dudimah Decl. ¶ 18). Plaintiff was charged with managing quality control of drug trials. Drug trials are highly sensitive due to the very nature of pharmaceutical research, public health, and private

medical information of drug trial participants. However, launching discovery into a substantial number of protocols on a class-wide basis would enable the acquirer of information to obtain cumulative research data that pose heightened risks of disclosure and misuse.

Further and as demonstrated above, Plaintiff has not shown a plausible case for class treatment. He does not offer anything more than a sparse and conclusory statement that other employees worked under similar conditions and schedules, and shared the same duties. He does not identify a common policy or plan, primarily because one does not exist. As a remote employee, he would unlikely have any knowledge as to other CRAs' day-to-day duties and schedules – specifically the rest-break habits of CRAs who work in the comfort of their own home. Without more, discovery to establish a class would be inappropriate.

CONCLUSION

For the reasons stated, Covance respectfully requests that the Court grant Covance's Motion to strike the class allegations in Plaintiff's Amended Complaint with prejudice.

Dated: New York, New York
November 6, 2017

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